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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/868,502

02/07/2002

Rolf M. Flugel

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BUCHANAN INGERSOLL PC  
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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/868,502

**Applicant(s)**

FLUGEL ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-24 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12 and 17-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 October 2005 has been entered.

This action is on claims 1-3, 5-12 and 17-24.

### ***Rejections Withdrawn***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 8 was rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining a full length FeFV clone, and it does not appear to be readily available material. Deposit of the full length FeFV clone would satisfy the enablement

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requirements of 35 U.S.C. 112. Applicant's deposit information in the specification does not indicate the extent of public availability.

Applicant has filed a new declaration for the deposit.

The declaration filed 7/28/05 has been fully considered.

The rejection is withdrawn.

Claims 1, 2, 4- 6, 8-12, and 17-20 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector comprising a full length clone of FeFV, does not reasonably provide enablement for vectors containing only a portion of the genome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant's arguments have been considered and the rejection is withdrawn.

### ***Claim Rejections - 35 USC § 103***

Claims 1-12, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al.* (Journal of Virology 1997, Vol. 71, pages 6727- 6741, from IDS) and Schmidt *et al.* (Virology 1995, Vol. 210, pages 167- 178, from IDS) further in view of Coffin *et al.*, eds, Retroviruses pages 437-441.

The rejection is withdrawn in favor of the new rejection presented below.

### ***New Rejections***

***Claim Rejections - 35 USC § 103***

Claims 1-3, 5-12, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al.* (Journal of Virology 1997, Vol. 71, pages 6727- 6741, from IDS) and ter Meulen *et al.* (US 5646032)

The invention is drawn to a retroviral vector for introducing a expressable DNA sequence in a mammal comprising a first DNA sequence comprising at least part of a reverse transcript of the FeFV genome corresponding to the 3' and 5' regions, and a second DNA sequence comprising a DNA sequence that allows propagation in bacteria. The dependent claims also cover infectious clones, heterologous gene inserts and deletions or inactivations of the Bel1 transactivator.

ter Meulen *et al.* teach the invention essentially as claimed. They teach a foamy virus infectious replication competent and replication incompetent foamy virus vectors that express foreign genes (column 1), that heterologous sequences can be expressed by the LTR and that if the Bel1 transactivator is deleted, it makes the vector safe and replication incompetent (column 2, lines 25-35 and 54-61).

ter Meulen *et al.* do not teach Feline foamy virus (FeFV).

Winkler *et al.* teach a full length clone of FeFV (by way of the clones used to generate sequences, Figure 1) and teach that it can be used to make vectors for targeted gene delivery (page 6740, column 1, top).

One of ordinary skill in the art at the time of invention would know about construction of foamy virus vectors as taught by ter Meulen *et al.* and could use the detailed information in Winkler *et al.* to construct FeFV vectors because Winkler *et al.* teach the sequence of FeFV. It is well known in the art that retroviral vectors are used to express or deliver foreign genes. One of ordinary skill in the art would be motivated to make a FeFV retroviral vector to study foamy viruses in vivo as taught by Winkler *et al.* (page 6727, last paragraph of introduction). Knowing the full length sequence and having the partial clones of Winkler *et al.* it would have been obvious to make a plasmid that contains a full length proviral clone. It appears that the sequence of the clone of claim 8 which is taught in Example 1 that results in the deposited pFeFV-7 is the same cloned viral sequence as the fully described clone of Winkler *et al.* One of ordinary skill in the art at the time of invention would have known that helper dependent viruses of ter Meulen *et al.* (column 1, lines 50-53) that use a packaging cell would be deleted in the structural genes (gag, pol, env) and those deleted genes would be provided by the packaging cell. One of ordinary skill in the art at the time of invention would have known that the expressible DNA could be inserted in the genome in place of the deleted region and this could be controlled by the FeFV promoter or a heterologous promoter (column 1, lines 25-28).

Thus, it would have been prima facie obvious to make a FeFV retroviral vector with the clone of Winkler *et al.* with the expectation of success knowing that vectors can be made from foamy viruses as taught by ter Meulen *et al.*


**Conclusion**

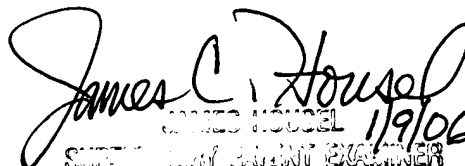
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
3 January 2005

  
JAMES HOUSEL 1/9/06  
SUPERVISOR  
TECHNOLOGY CENTER 1600